

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG,	)	
ABBOTT BIORESEARCH CENTER, INC.,	)	C.A. No. 4:09-CV-11340 (FDS)
AND ABBOTT BIOTECHNOLOGY LTD.,	)	
	)	
Plaintiffs,	)	JURY TRIAL DEMANDED
	)	
v.	)	
	)	
CENTOCOR ORTHO BIOTECH, INC., AND	)	
CENTOCOR BIOLOGICS, LLC.	)	
	)	
Defendants.		

**CENTOCOR BENCH MEMORANDUM ON  
THE LEGAL TEST FOR WRITTEN DESCRIPTION**

To satisfy the written description requirement for a genus claim, the patent specification must disclose either 1) a representative number of species (or specific examples) falling within the scope of the genus or 2) structural features common to the members of the genus so that one of skill in the art can “visualize or recognize” the members of the genus. *Regents of Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997) (Ex. 1). Abbott has conceded that its patents do not disclose structural features common to the members of the claimed genus; thus, a focus in the case has been whether the patents disclose representative species. When there is substantial variation within the genus, the specification must describe a sufficient variety of species to reflect the variation within the genus. *Carnegie Mellon Univ. v. Hoffman-La Roche, Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) (Ex. 2).

Abbott’s argument in its motion for judgment as a matter of law that Centocor’s written description defense collapses the “representative species” test and the “structural features” test (D.I. 475 at 4) into one is wrong. The numerous and meaningful structural differences between Centocor’s Stelara® and Abbott’s Joe 9/J695 antibodies are relevant as they evidence the wide variety of the members within the claimed genus, and that variety must be considered in determining whether “representative” examples are provided in the patent. In considering the variability of the structures of the antibodies encompassed within Abbott’s claims, including comparing the structures of the exemplified antibodies to the structures of those not exemplified in the patent, Centocor is asking the jury to consider just what the *Carnegie Mellon* court considered when it concluded that there was substantial variation within the claimed genus and that there was an insufficient variety of species disclosed to reflect that variation.

Specifically, the claim in *Carnegie Mellon* was directed to plasmids (pieces of DNA) that were broadly defined only by their function, *viz.*, encoding enzymes called DNA polymerase I

from bacteria. *Id.* at 1123-1124. The generic claims were not limited to DNA coding sequences encoding enzymes in a single bacterial species; rather, they broadly encompassed DNA coding sequences originating from any bacterial species.<sup>1</sup> The patent disclosed the DNA coding sequence for only one bacteria, *E. coli*. *Id.* at 1125.

In considering whether the patent contained representative examples, the Court discussed the *structural* variation within the claimed genus. It noted for example, that the claimed DNA coding sequence (“polA gene”) “varied among the numerous bacterial species” and “has different *sequences* for probably all the different bacterial species.” *Id.* at 1125-27 (emphasis added). The court expressly compared the *sequences* of DNA from other bacteria species within the claimed genus to that for the one species disclosed, *E. coli*, and noted that the former was “distinct from” the latter. *Id.* at 1125. It concluded that the written description requirement was not met because of the variation within the claimed genus and because the single disclosed embodiment was not representative of, and failed to adequately support, the entire claimed genus. *Id.* at 1126.

The *Carnegie Mellon* court’s consideration of the variety among the structures of the species subsumed by the claimed genus in the context of determining whether the “representative examples” test is met dispatches Abbott’s argument that Centocor, in asking the jury to do the exact same thing, is somehow “collapsing” the tests for written description of a genus. Abbott’s argument suggesting that Centocor is misapplying or “collapsing” the written description test by focusing on structural dissimilarity within Abbott’s claimed genus, or that such evidence is not

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<sup>1</sup> Just as proteins, like antibodies, are made up of amino acid building blocks and have an “amino acid sequence,” DNA is made up of nucleotide building blocks and has a “nucleotide sequence.”

properly considered in determining the variability of the genus, is legally erroneous. Such argument can only mislead and confuse the jury and should not be permitted.

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By: *Dianne Elderkin*

Dianne B. Elderkin (pro hac vice)

delderkin@akingump.com

Barbara L. Mullin (pro hac vice)

bmullin@akingump.com

Steven D. Maslowski (pro hac vice)

smaslowski@akingump.com

Angela Verrecchio (pro hac vice)

averrecchio@akingump.com

Matthew A. Pearson (pro hac vice)

mpearson@akingump.com

AKIN GUMP STRAUSS HAUER & FELD LLP

Two Commerce Square

2001 Market Street, Suite 4100

Philadelphia, PA 19103-7013

215-965-1200

FAX: 215-965-1210

Emily C. Johnson (pro hac vice)

johnsone@akingump.com

AKIN GUMP STRAUSS HAUER & FELD LLP

Robert S. Strauss Building

1333 New Hampshire Avenue N.W.

Washington, DC 20036

Heather B. Repicky (BBO # 663347)

NUTTER MCLENNEN & FISH LLP

World Trade Center West

155 Seaport Boulevard

Boston, MA 02210

617-439-2000

FAX: 617-310-9000

Attorneys For Defendants

CENTOCOR ORTHO BIOTECH, INC. and

CENTOCOR BIOLOGICS, LLC

**CERTIFICATE OF SERVICE**

I certify that, on September 20, 2012 this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

/s/ Angela Verrecchio